

## **Remarks**

Claims 12-14 are pending. Claims 1-11 and 15-20 have been canceled without prejudice. Therefore, no new matter has been added. Favorable reconsideration is respectfully requested in view of the following remarks.

### **Response to Claim Rejections**

#### ***U.S. Patent Application Publication No. 2002/0137973***

Claims 12-14 stand rejected under 35 U.S.C. § 102(b) and 35 U.S.C. § 103(a) based on the Examiner's contention that they are anticipated or rendered obvious by U.S. Patent Publication No. 2002/0137973 to Reeve et al. (the "'973 publication"). Specifically, the Examiner contends that the rejected claims read on the '973 publication. The Applicants respectfully disagree.

First, the Applicants respectfully point out that the Examiner has improperly cited the '973 publication as prior art. Specifically, as delineated on page 1 of the instant application, the instant application is a continuation in part of U.S. patent application No. 10/766,756 which is a continuation of U.S. patent application No. 09/928,560 (which published as the '973 publication), which claims the benefit of U.S. provisional application No. 60/225,917. All three applications are incorporated by reference in their entirety. Therefore, the '973 publication, to which the instant application claims priority, cannot properly be used as the basis of an anticipation or obviousness rejection. Accordingly, the Applicants respectfully request the withdrawal of the claim rejections under 35 U.S.C. § 102(b) and § 103(a) based upon the '973 publication.

#### ***U.S. Patent No. 5,800,711***

Claims 12-14 stand rejected under 35 U.S.C. § 102(b) based on the Examiner's contention that they are anticipated by U.S. Patent No. 5,800,711 to Reeve et al. Specifically, the Examiner contends that the rejected claims read on the '711 patent. The Applicants respectfully disagree. The Applicants respectfully assert that claim 12 is not anticipated by the '711 patent. Importantly, the '711 patent is silent with respect to the polyoxyalkylene block copolymers and their temperature-dependent viscosities, as required by claim 12. The Applicants respectfully remind the Examiner that in order to anticipate a claim, a single source

must contain all of the elements of the claim. See *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379, 231 U.S.P.Q. 81, 90 (Fed. Cir. 1986); *Atlas Powder Co. v. E.I. duPont De Nemours & Co.*, 750 F.2d 1569, 1574, 224 U.S.P.Q. 409, 411 (Fed. Cir. 1984); *In re Marshall*, 578 F.2d 301, 304, 198 U.S.P.Q. 344, 346 (C.C.P.A. 1978).

Specifically, claim 12 requires that the viscosity of an aqueous solution of the polyoxyalkylene block copolymer increases by at least a factor of two over a temperature range of about 2 °C. The '711 patent provides in Figure 2 “a graphical comparison of the viscosity profiles of various concentrations on commercial poloxamer 407 and fractionated poloxamer 407” produced with the methods of the '711 patent. Importantly, none of the fractionated samples of poloxamer 407 in Figure 2 displays a viscosity increase of at least a factor of two over a temperature range of about 2 °C.

Nevertheless, the Examiner alleges that the viscosity required in claim 12 would “appear to be achieved by purifying the copolymers.” The Examiner contends that inasmuch as the '711 patent “purif[ies] the recited copolymers, they would all appear to have the recited viscosity.” The Applicants strongly disagree. The '711 patent does not recite or purify all of the polyoxyalkylene copolymers recited in claim 12. Nowhere in the '711 patent does Reeve achieve the temperature-dependent viscosity of claim 12. The Applicants respectfully remind the Examiner that missing elements may not be supplied by the knowledge of one skilled in the art or the disclosure of another reference. See *Structural Rubber Prods. Co. v. Park Rubber Co.*, 749 F.2d 707, 716, 223 U.S.P.Q. 1264, 1271 (Fed. Cir. 1984).

Furthermore, the doctrine of “[i]nherent anticipation requires that the missing descriptive material is ‘necessarily present,’ not merely probably or possibly present, in the prior art.” *Trintec Indus., Inc. v. Top-U.S.A. Corp.*, 295 F.3d 1292, 1295 (Fed. Cir. 2002) (quoting *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999)). Elaborating on this precedent, the MPEP points out that “[i]n relying upon the theory of inherency, the [E]xaminer must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art.” MPEP § 2112 (quoting *Ex parte Levy*, 17 U.S.P.Q.2d 1461, 1464 (B.P.A.I. 1990) (emphasis in original)). With respect to the '711 patent, the Applicants respectfully assert that the Examiner has not met the evidentiary burden to invoke the doctrine of inherency because the methods of Reeve do not

achieve the required viscosities. Therefore, claim 12 is not anticipated inherently by the '711 patent because the prior art disclosure does not necessarily produce the claimed composition.

The Applicants contend that rejected claims 13 and 14 are not anticipated by the '711 patent because the claims depend upon claim 12. Accordingly, the Applicants respectfully request the withdrawal of the claim rejections under 35 U.S.C. § 102(b) based upon the '711 patent.

Claims 12-14 also stand rejected under 35 U.S.C. § 103(a) based on the Examiner's contention that they are rendered obvious by the '711 patent. Specifically, the Examiner contends that the rejected claims read on the individual Reeve references or the combination of them. The Applicants respectfully disagree. The '711 patent is silent with respect to the purification of all of the polyalkylene block copolymers encompassed by claim 12. Specifically, the '711 patent is silent with respect to the purification of poloxamer 338, poloxamer 288, poloxamer 238, poloxamine 1107 or poloxamine 908. Moreover, the '711 patent is silent with respect to the polyoxyalkylene block copolymers and their requisite viscosities required by claim 12. The Applicants respectfully maintain that the Examiner has failed to establish the required *prima facie* showing of obviousness with respect to the rejected claims. See MPEP § 2143.03 (“[t]o establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981.”).

The Examiner contends that optimization of the elements of the Reeve references would have been obvious to try to enhance separation. The Applicants respectfully disagree. The Applicants contend that the claimed invention possesses unexpectedly improved properties over the '711 patent, particularly when comparing the methods of purification and the data presented in Figure 2 to the properties of the fractionated polymers of the instant invention. *Specifically, the methods of purification of poloxamer 407 demonstrated in the '711 patent (Examples 1 and 2, column 7, line 16 through column 8, line 40) produce fractionated poloxamer 407 that does not display a viscosity increase of at least a factor of two over a temperature range of about 2 °C.* The methods disclosed in Examples 1 of the '711 patent indicate that at least seven extractions are required to obtain a fractionated poloxamer 407. The Applicants direct the Examiner to Figure 2 of the '711 patent which depicts the viscosity changes of a 28% solution of fractionated poloxamer purified by the methods of the aforementioned Examples 1 and 2 of the

'711 patent. Notably, when the temperature changes from 15 °C to 17.5 °C (about 2 °C), the viscosity changes from about 300 to about 425 Kcps; an increase which is less than a factor of two.

By comparison, the purification of poloxamer 407 utilizing the methods of the instant application, as described in detail in Example 2 (page 17 of the instant application), demonstrates that with only four extractions the fractionated purified poloxamer 407 obtained is unexpectedly superior to the fractionated poloxamer 407 prepared using the methods of the '711 patent. Specifically, the Applicants submit that the data in Figure 2 of the instant application demonstrates that when the temperature of a 25% solution of fractionated poloxamer 407 of the present invention is raised from 15 °C to 17.5 °C (about 2 °C), the viscosity of the solution changes from about 150 to about 500 Kcps.

The Applicants respectfully submit that with knowledge only of the fractionation process of the '711 patent, one of ordinary skill in the art would not expect to achieve the fractionation and corresponding viscosities obtained via the methods of the instant invention, as it is well known in the art that "it usually takes several extractions to remove a solute from a solvent," and that successive extractions can result in removal of significantly more solute. *See Pavia, Lampman, Kriz and Engel, Introduction to Organic Laboratory Techniques Second Edition*, p 642, (Saunders 1995). Thus, if seven extractions are required to achieve the level of purity depicted in Figure 2 of the '711 patent, the Applicants submit that one of ordinary skill in the art would not expect that less than seven extractions would lead to an improved purification and enhanced separation as the Examiner contends.

Accordingly, the Applicants respectfully request the withdrawal of the claim rejections under 35 U.S.C. § 103(a) based upon the '711 patent.

***U.S. Patent No. 5,531,925; 6,448,371; and U.S. Patent Application Publication No. 2005/0008610***

Claims 12-14 stand rejected under 35 U.S.C. § 102(b) or 35 U.S.C. § 103(a) based on the Examiner's contention that they are anticipated or rendered obvious by U.S. Patent No. 6,448,371 to Berg et al. ("Berg"), U.S. Patent No. 5,531,925 to Landh et al. ("Landh"), and U.S. Publication No. 2005/008610 to Schwarz et al. ("Schwarz"), or the combination of them. Specifically, the Examiner contends that the rejected claims read on the individual references or

the combination of them. The Applicants respectfully disagree. The Applicants respectfully assert that claim 12 is not anticipated nor rendered obvious by any of the Landh, Berg, and Schwarz references, or the combination of them.

### *The Berg Patent*

The Applicants respectfully remind the Examiner that in order to anticipate a claim, a single source must contain all of the elements of the claim. See *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379, 231 U.S.P.Q. 81, 90 (Fed. Cir. 1986); *Atlas Powder Co. v. E.I. duPont De Nemours & Co.*, 750 F.2d 1569, 1574, 224 U.S.P.Q. 409, 411 (Fed. Cir. 1984); *In re Marshall*, 578 F.2d 301, 304, 198 U.S.P.Q. 344, 346 (C.C.P.A. 1978). Importantly, the Berg reference is silent with respect to the polyoxyalkylene block copolymers and their temperature-dependent viscosities, as required by claim 12.

The Examiner alleges that the viscosity required in claim 12 would “appear to be achieved by purifying the copolymers.” The Examiner contends that inasmuch as the Berg patent “purif[ies] the recited copolymers, they would all appear to have the recited viscosity.” The Applicants strongly disagree. Berg does not recite or purify all of the polyoxyalkylene copolymers recited in claim 12. Nowhere in the Berg patent does Berg achieve the temperature-dependent viscosity of any of the polymers claimed in the instant application. The Applicants respectfully remind the Examiner that missing elements may not be supplied by the knowledge of one skilled in the art or the disclosure of another reference. See *Structural Rubber Prods. Co. v. Park Rubber Co.*, 749 F.2d 707, 716, 223 U.S.P.Q. 1264, 1271 (Fed. Cir. 1984).

The doctrine of “[i]nherent anticipation requires that the missing descriptive material is ‘necessarily present,’ not merely probably or possibly present, in the prior art.” *Trintec Indus., Inc. v. Top-U.S.A. Corp.*, 295 F.3d 1292, 1295 (Fed. Cir. 2002) (quoting *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999)). Elaborating on this precedent, the MPEP points out that “[i]n relying upon the theory of inherency, the [E]xaminer must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art.” MPEP § 2112 (quoting *Ex parte Levy*, 17 U.S.P.Q.2d 1461, 1464 (B.P.A.I. 1990) (emphasis in original)). With respect to the Berg patent, the Applicants respectfully assert that the Examiner has not met the evidentiary burden to invoke the doctrine of inherency because the methods of Berg do not

demonstrably achieve the purification necessary to obtain the required viscosities. Therefore, claim 12 is not anticipated inherently by the Berg patent because the prior art disclosure does not necessarily produce the claimed composition.

The Applicants contend that rejected claims 13 and 14 are not anticipated by the Berg patent as the claims depend upon claim 12. Accordingly, the Applicants respectfully request the withdrawal of the claim rejections under 35 U.S.C. § 102(b) based upon the Berg patent.

#### *The Landh Reference*

The Applicants respectfully remind the Examiner that in order to anticipate a claim, a single source must contain all of the elements of the claim. *See Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379, 231 U.S.P.Q. 81, 90 (Fed. Cir. 1986); *Atlas Powder Co. v. E.I. duPont De Nemours & Co.*, 750 F.2d 1569, 1574, 224 U.S.P.Q. 409, 411 (Fed. Cir. 1984); *In re Marshall*, 578 F.2d 301, 304, 198 U.S.P.Q. 344, 346 (C.C.P.A. 1978). Importantly, the Landh reference is silent with respect to the polyoxyalkylene block copolymers and their requisite temperature-dependent viscosities recited in claim 12. At column 11, line 42, Landh indicates that for the method of the invention (preparation of a glycerol monooleate water system), the inventors utilized a commercially available purified poloxamer 407. Consequently, the Applicants respectfully submit that Landh fails to describe the characteristics of said poloxamer 407, or demonstrate purification of any other polyoxyalkylene block copolymers.

The Examiner alleges that the viscosity required in claim 12 would “appear to be achieved by purifying the copolymers.” The Examiner contends that inasmuch as the Landh patent “purif[ies] the recited copolymers, they would all appear to have the recited viscosity.” The Applicants strongly disagree. Landh does not recite or purify all of the polyoxyalkylene copolymers recited in claim 12. Nowhere in the Landh patent does Landh achieve the temperature-dependent viscosity of any of the copolymers claimed in the instant application. The Applicants respectfully remind the Examiner that missing elements may not be supplied by the knowledge of one skilled in the art or the disclosure of another reference. *See Structural Rubber Prods. Co. v. Park Rubber Co.*, 749 F.2d 707, 716, 223 U.S.P.Q. 1264, 1271 (Fed. Cir. 1984).

The doctrine of “[i]nherent anticipation requires that the missing descriptive material is ‘necessarily present,’ not merely probably or possibly present, in the prior art.” *Trintec Indus.*,

*Inc. v. Top-U.S.A. Corp.*, 295 F.3d 1292, 1295 (Fed. Cir. 2002) (quoting *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999)). Elaborating on this precedent, the MPEP points out that “[i]n relying upon the theory of inherency, the [E]xaminer must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art.” MPEP § 2112 (quoting *Ex parte Levy*, 17 U.S.P.Q.2d 1461, 1464 (B.P.A.I. 1990) (emphasis in original)). With respect to the Landh patent, the Applicants respectfully assert that the Examiner has not met the evidentiary burden to invoke the doctrine of inherency because the methods of Landh do not demonstrably achieve the purification necessary to obtain the required viscosities. Therefore, claim 12 is not anticipated inherently by the Landh patent because the prior art disclosure does not necessarily produce the claimed composition.

The Applicants contend that rejected claims 13 and 14 are not anticipated by the Landh patent as the claims depend upon claim 12. Accordingly, the Applicants respectfully request the withdrawal of the claim rejections under 35 U.S.C. § 102(b) based upon the Landh patent.

#### *The Schwarz Reference*

As discussed above, the Applicants respectfully remind the Examiner that in order to anticipate a claim, a single source must contain all of the elements of the claim. *See Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379, 231 U.S.P.Q. 81, 90 (Fed. Cir. 1986); *Atlas Powder Co. v. E.I. duPont De Nemours & Co.*, 750 F.2d 1569, 1574, 224 U.S.P.Q. 409, 411 (Fed. Cir. 1984); *In re Marshall*, 578 F.2d 301, 304, 198 U.S.P.Q. 344, 346 (C.C.P.A. 1978). Importantly, the Schwarz reference is silent with respect to the polyoxyalkylene block copolymers and their requisite temperature-dependent viscosities recited in claim 12.

The Examiner alleges that the viscosity required in claim 12 would “appear to be achieved by purifying the copolymers.” The Examiner contends that inasmuch as the Schwarz patent “purif[ies] the recited copolymers, they would all appear to have the recited viscosity.” The Applicants strongly disagree. Schwarz does not recite or purify all of the polyoxyalkylene copolymers recited in claim 12. Nowhere in the Schwarz reference does Schwarz disclose or discuss the temperature-dependent viscosity of any of the copolymers claimed in the instant application. The Applicants respectfully remind the Examiner that missing elements may not be supplied by the knowledge of one skilled in the art or the disclosure of another reference. *See*

*Structural Rubber Prods. Co. v. Park Rubber Co.*, 749 F.2d 707, 716, 223 U.S.P.Q. 1264, 1271 (Fed. Cir. 1984).

Moreover, the doctrine of “[i]nherent anticipation requires that the missing descriptive material is ‘necessarily present,’ not merely probably or possibly present, in the prior art.” *Trintec Indus., Inc. v. Top-U.S.A. Corp.*, 295 F.3d 1292, 1295 (Fed. Cir. 2002) (quoting *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999)). Elaborating on this precedent, the MPEP points out that “[i]n relying upon the theory of inherency, the [E]xaminer must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art.” MPEP § 2112 (quoting *Ex parte Levy*, 17 U.S.P.Q.2d 1461, 1464 (B.P.A.I. 1990) (emphasis in original)). With respect to the Schwarz reference, the Applicants respectfully assert that the Examiner has not met the evidentiary burden to invoke the doctrine of inherency because the methods of Schwarz demonstrably achieve the purification necessary to obtain required viscosities. Therefore, claim 12 is not anticipated inherently by the Schwarz reference because the prior art disclosure does not necessarily produce the claimed composition.

The Applicants contend that rejected claims 13 and 14 are not anticipated by the Schwarz reference as the claims depend upon claim 12. Accordingly, the Applicants respectfully request the withdrawal of the claim rejections under 35 U.S.C. § 102(b) based upon the Schwarz reference.

#### *Obvious to Try*

The Examiner contends that optimization of the processes of the Berg, Landh and Schwarz references would have been obvious to try to enhance separation and obtain the invention of claim 12. The Applicants respectfully disagree. Moreover, the Applicants contend that the Examiner is applying an improper “obvious to try” rationale in support of an obviousness rejection. In this case, the prior art provides no indication of which parameters are critical to obtain the temperature-dependent viscosities required by claim 12. Further, as discussed above, the prior art provides only general guidance as to purification. With no discussion of how the methods of purification subsequently affect the viscosity of the resulting polymers, one of ordinary skill in the art would not have been motivated to combine the three references to obtain the claimed invention.



Furthermore, the Applicants respectfully maintain that the combination of the Landh, Berg, and Schwarz references fails to teach all of the limitations of claim 12. Specifically, the Landh, Berg, and Schwarz references do not describe purification and resulting temperature-dependent viscosities of poloxamer 338, poloxamer 288, poloxamer 238, poloxamine 1107 or poloxamine 908, nor the change in viscosity resulting from purification of poloxamer 407. The Applicants maintain that the Examiner has failed to establish the required *prima facie* showing of obviousness with respect to the rejected claims. See MPEP 2143.03 (“[t]o establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981.”).

The Applicants contend that rejected claims 13 and 14 are not rendered obvious by the Landh, Berg, or Schwarz references or the combination of them as the claims depend upon claim 12. Accordingly, the Applicants respectfully request the withdrawal of the claim rejections under 35 U.S.C. § 103(a) based upon any of the Landh, Berg, and Schwarz references or the combination of them.

### **Fees**

The Applicants believe that no fee is due in connection with the filing of this Response. Nevertheless, the Commissioner is hereby authorized to charge any fees due in connection with the filing of this Response to our Deposit Account, **No. 06-1448, reference PMX-003.02.**

### **Conclusion**

The Applicants believe that the pending claims are in condition for allowance. If a telephone conversation with Applicants' Attorney would expedite prosecution of the above-identified application, the Examiner is urged to contact the undersigned.

Respectfully submitted,  
Foley Hoag LLP

By: \_\_\_\_\_



Dana M. Gordon, Ph.D.  
Reg. No. 44,719  
Attorney for Applicants

155 Seaport Boulevard  
Boston, MA 02210

Telephone: (617) 832-1000  
Telecopier: (617) 832-7000

Date: \_\_\_\_\_

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